ArtAssist® ...*the Arterial Assist Device*™

Model AA-1000

Operations and Service Manual

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AD2-00201 and above

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INTRODUCTION

When you finish reading this operations and service manual, you will become an ArtAssist® Model AA-1000 expert! Well, maybe not an expert, but our hope at ACI Medical, LLC. is to provide you with an informative manual to answer any questions you might have regarding this device. This manual is filled with important information, useful tips and enlightening pictures to help you.

GENERAL DESCRIPTION

The ArtAssist® device is the only external pneumatic compression device developed with vascular surgeons for the sole purpose of increasing blood circulation and specifically, arterial blood flow. It applies impulse pressure to the foot, ankle, and calf. Single-patient-use cuffs are made of soft durable material designed to last for months of therapy. Therapy takes place with the patient in a comfortable sitting position. The patient only needs to turn the device on since all pressure and timing controls are pre-set and hidden from the patient. It is portable and suitable for home, clinic or hospital use.

This device significantly increases patients' blood flow in the popliteal artery and at the tissue level.[1,3,5,6,11] Improvements were observed in calf blood flow using duplex ultrasonic imaging and APG® Air-Plethysmography.[2] Further, it has been shown that calf and foot region compression increases volumetric blood flow by better than three times that of foot-only compression as measured by duplex ultrasonography.[3] Venous return flows are increased over 5 times in muscular, superficial and deep veins.[12] ArtAssist® has saved limbs in severe cases where amputations below the knee were expected.[4,10]

ArtAssist® is composed of three basic components: an electrically operated controller, tubing sets that conduct the air pulses from the controller to the cuffs and single patient use limb cuffs. The controller is connected to a wall outlet for power using the included power cord. Either one or two pneumatic limb cuffs can be attached to the controller via pneumatic fittings. The cuffs are for use on either left or right limbs and are "one size fits all." The only control available to the user of the controller is an ON-OFF power switch that illuminates when power is applied. Pressure and time parameters have been optimized for the population of ischemic patients; but in rare cases, the applied pressure may be altered by opening the front panel.

In three separate studies, this device was shown to significantly improve pain free walking distance in patients with intermittent claudication and that those improvements were long-lasting after therapy was discontinued.

HOW TO GET STARTED

1. Unpack items and SAVE ALL PACKING MATERIALS AND PAPERWORK. You will need this to return the device to ACI.

2. Place controller by a chair for use in therapy.

3. Plug power cord into a wall outlet and the opposite end into controller, located on the lower side.

4. Plug the tubing set with the black plastic connector at the end into the upper side of the controller. Plug all the way in.

5. Connect the other end of the tubing set into the compression cuff. Plug barb fittings labeled "To Foot Cuff" into the foot cuff and "To Calf Cuff" into the calf cuff.

6. Keep any wound healing bandages in place and apply a white athletic sock on the feet to be treated.

7. Wrap compression cuffs around foot, ankle, and calf as shown on pictorial instruction card or on the Instructional VHS/DVD.

8. Sit with feet on the floor and then turn on power switch on the controller to begin therapy.

9. After 1-hour therapy, the controller will stop compressing and "TIMED OUT" will appear on the controller near the power switch. Removed cuff(s) and store until the next therapy session.

10. Typically therapy consists of 1-hour compression, 3 times a day (morning, afternoon and evening). Your doctor may prescribe a different usage for you.

INDICATIONS

This device is adjunct therapy for patients with ischemic disease of the lower limbs.

It is indicated for patients with poor circulation including:

* REST PAIN, NIGHT PAIN
* INTERMITTENT CLAUDICATION
* SMALL VESSEL DISEASE
* ARTERIOPATHIC WOUNDS
* MINOR AMPUTATIONS
* ULCERS
* ISCHEMIA
* GRAFT FAILURE
* ANGIOPLASTY/STENT FAILURE

CONTRAINDICATIONS

1. Infected limbs
2. Limbs with suspected deep vein thrombosis or arterial clots
3. During episodes of inflammatory phlebitis or pulmonary embolism
4. When increased venous and lymphatic return is undesirable (such as congestive heart failure)

Precaution: For use only under medical supervision. This device is restricted to sale by or on the order of a physician.

SAFETY CONSIDERATIONS

SAFETY FEATURES:

- The device is safety fused for:
  1. Excessive current consumption by the controller
  2. Excessive current consumption by only the internal pump
- Alarms will sound if there are any problems concerned with overpressure, under pressure, air leaks, power supplies, and pump temperature.
- A cooling fan is installed for temperature stability.
- In an alarm condition, power is removed from the pump and solenoid valves, which exhausts pressure from all cuffs. The cooling fan remains on.
- If the unit loses power, all cuffs exhaust.

SAFETY WARNINGS:

- Compression cuffs must be removed before walking or the patient MAY SLIP AND FALL.
- Apply the cuffs over bandages and clean white cotton socks.
- ArtAssist® is to be used by the patient only. It is not to be used for any other person, nor for any other purpose than as prescribed by the Physician.
- The patient should contact their Physician if they notice a change of skin condition at or near the sites of the cuff, such as any rash, redness, blister, etc. The patient should examine the site before and after use.
- Proper use of the device is to be monitored by the patient and Physician, and not by ACI.
- ELECTRICAL HAZARD: Do not operate in wet areas or with wet hands, feet, etc.
- Avoid spilling any liquids onto the control units. This can cause possible damage to the unit.
- After therapy, be sure to put it in a safe place and out of reach of children.
- If rented, return the device and accessories to ACI promptly after Physician orders discontinuation of its use.
- Stop use if alarm sounds and refer to Trouble Shooting section.
- There is no known potential electromagnetic or other inference between the ArtAssist® device and other devices.

LABELS

On Top Of Controller

ArtAssist®*...the Arterial Assist Device™*
Produced under license by ***Dr. Paul S. van Bemmelen.***

ACI Medical, LLC.

90-2492-001

On Bottom Of Controller

DANGER Risk of electric shock. Disconnect power cord before opening or servicing this device.

WARNINGS
1. Only qualified service personnel should repair this device. Improper repair may result in serious injury, death, equipment damage or malfunction.
2. For continued protection against fire and shock hazards, replace internal fuses only with same type and rating (GMA 1.0 Amp).

90-2491-001

On Side Of Controller

Abbreviated Instructions Refer to the instruction manual for further details.

1. Apply compression cuff to affected limb over all bandages and clean socks. Do not allow compression cuff to contact broken, irritated or ulcerated skin.
2. Attach the cuff's hoses to appropriate connectors and into the control unit. Observe labels for "foot" and "calf" for proper attachments.
3. Sit in a comfortable chair with legs resting in a downward position or on the floor.
4. Apply power with the POWER switch located on the front panel. The switch will illuminate to show the device is on. The controller will turn off automatically after one hour.
5. Check for skin condition changes after each use and notify physician of any worsening.
6. Clean this control unit with a damp cloth containing mild disinfectant solutions or detergents and water.
7. Use this device only as prescribed by your doctor. Do not use for any other purpose or on other individuals.

Front Panel Lights

TIMED OUT will light after the controller has operated for one hour. Turn the power switch to OFF and then back to ON when compression therapy is to resume.
REPAIR LEAK will light when the controller cannot operate at the proper pressure. Check the cuffs, tubing and connectors for possible leaks.
REPAIR will light when there is something wrong with the controller that can only be repaired by qualified service personnel. Call for service.

CAUTIONS

1. Use under medical supervision.
2. Federal law restricts this device to sale by or on the order of a physician.
3. While using oxygen, position this device only at the foot of the bed or as far as possible from equipment administering oxygen.

CONTRAINDICATIONS Do not prescribe or use this device:

1. During episodes of inflammatory phlebitis or pulmonary embolism;
2. When deep vein thrombosis is diagnosed or suspected;
3. When increased venous or lymphatic return is undesirable including presumptive evidence of congestive heart failure;
4. On limbs with uncontrolled infection;
5. When pain increases significantly or with worsening skin tissue condition.

PRECAUTIONS

1. The doctor is advised to make frequent observations of treated limbs for skin lesions and signs of infection.
2. Use of ArtAssist® with acute arterial thrombi may cause distal embolization.

DANGER **Risk of explosion. Do not use this device in the presence of flammable anesthetics or other flammable gases.**

DANGER For grounding reliability, plug only into a three pronged grounded outlet. When used in a health care facility, use only with an outlet labeled "Hospital Grade."

US pat. no. 5,218,954. Israel pat. no. 106,258. RSA pat. No. 93/4841. Other US and foreign pat's. pending.

90-2493-001 ACI Medical, LLC., San Marcos, CA, USA Tel. 888-4 LEG FLO **115V, 60Hz, 0.4A**

PHYSICAL DESCRIPTION

ArtAssist® Model AA-1000

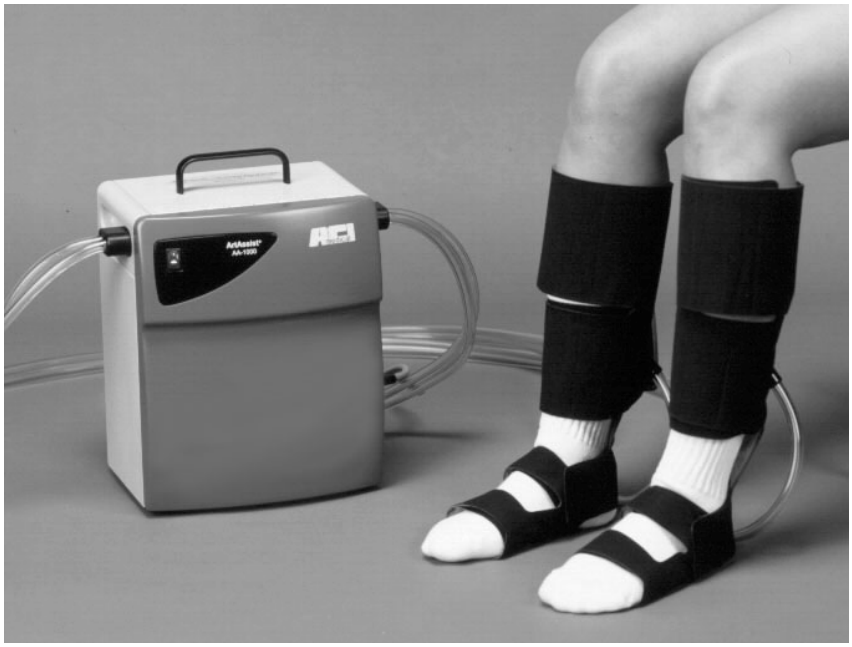

Figure 1

1. **Controller**
   Specifications (Unilateral or Bilateral* System)

Operating Voltage	**Model Number**	**Max. Current**
115 V, 60 Hz	AA-1000	0.4 Amps
220 V, 50 Hz	AA-1000e	0.2 Amps
100 V, 60 Hz	AA-1000n	0.5 Amps

Maximum Operating Temperature: 85º F degrees

Power cord – at least 6 feet long, hospital grade plug, universal female

Size – 10” wide, 12” high, 7 ¾ deep. The top handle adds 1 ¼” in height.

Weight – 23 pounds, controller only

Indicators – Located in “black-out” on the front panel’s black bezel just to the right of the power switch.

TIMED OUT indicates the device has been continuously in use for about one hour.

REPAIR LEAK indicates an under pressure condition, most likely due to an air leak somewhere in the system. Check for leaks in the cuffs, tubing and connectors. The pump may be malfunctioning or there may be a leak elsewhere in the system. It takes between 170 and 290 seconds of a leak condition to activate the alarm.

REPAIR indicates that there is a problem in the system that is not leak related. Refer to the Trouble Shooting section.

Generally, cycling the controller's power by turning it off then back on will reset the indicators.

2. **Tubing sets** – Two included in bilateral system. Six feet long, ¼"ID, ½"OD vinyl, dual lumen with keyed, proprietary connector for attaching to the controller and barb fittings to attach to the cuffs.
3. **Compressions cuffs** – FOR SINGLE PATIENT USE ONLY. Two tubing sets and compression cuffs are included in a bilateral system.
    1. Outside surface – Heavy-duty nylon tricot of hook-compatible loop with polymer lamination for air bladder integrity. There are two internal bladders: one for the foot and ankle regions; another for the calf region.
    2. Inside surface – Napp nylon tricot cloth with polymer lamination.
4. **Instructions –** An instructional video (DVD), pictorial instruction sheet and operations and service manual are supplied with all units.

Note: Instruction manuals are not included with rental units because the VHS/DVD and pictorial instruction sheet are sufficient for proper operation. Most physicians wish the patient to be unaware of the internal clock that monitors patient compliance.

INTERNAL PRESSURE ADJUSTMENT AND PATIENT COMPLIANCE ASSESSMENT

Pressure Adjustment

The ArtAssist® device has undergone clinical testing[13] to determine the optimal timing and pressure settings for maximizing the increase of arterial inflow. The timing parameters are therefore not adjustable. However, patients with ischemic rest pain or other conditions may experience discomfort from the factory pre-set pressure of 120 mmHg. When that is the case, the **pressure may be reduced by the clinician only,** by turning the pressure regulator knob counter clockwise. Compression with a lower pressure may reduce the patient's pain and allow for gradual increase of pressure back to 120 mmHg as the patient is able. Make pressure changes by only using a pressure gauge, provided through ACI. Call 8884 LEG FLO to borrow a pressure gauge at no charge. The front panel is opened by removing the two screws located on the bottom of the controller toward the front. Be sure to disconnect the power cord from the controller before opening the front panel.

For instructions to adjust pressure, refer to page 25 in this manual.

Timing Settings

All timing parameters have been established based upon clinical studies and are preset at the factory. They are changeable only at the factory.
Compression Time: 3 seconds, +/- 0.5 seconds.
Non-Compression Time: 17 seconds, +/- 3 seconds.
DELAY between foot/ankle and calf bladders: 1 second, +/- 0.5 seconds.
Pressure Rise and Fall Times: approximately 300 msec, +/- 100 msec.

Patient Compliance Assessment

The Run time hour meter is located under the front panel toward the left side. It reads out total time the controller is operated and cannot be reset. This is a tamper proof feature. Patient compliance can be easily assessed by subtracting successive meter readings. ACI records the meter reading before the device is shipped. This reading is available to clinicians by calling ACI. Please provide the serial number, patient name or prescribing doctor's name.

Close the panel using the screws to prevent further access.

MAINTENANCE

The device requires little maintenance, but it is recommended that hospitals maintain the unit as required by hospital safety regulations. For home use, ACI recommends the cleaning of the exterior case and tubing with a damped cloth of mild soap and water or alcohol between different patient's use.

Suggested Cleaning Procedure for Hospital Use

1. Clean the device between different patient's use or after 1-month by the same patient.
2. Wipe all areas of the device using a cloth and an EPA registered hospital-grade disinfectant following the manufacturer's Material Safety Data Sheet. It is recommended that hospital gloves be used to prevent the possible spread of infections.
3. Clean all visible soiling.
4. If blood or body fluids are present on the device, follow the 2 step cleaning process recommended by OSHA.
    a) Apply an EPA registered tuberculocidal disinfectant. Remove and clean all visible soil.
    b) Wipe down with 1:100 sodium hypochlorite solution.
5. Remove gloves and wash hands thoroughly.
6. Allow the device to dry before reusing.

The pressure delivered to the cuffs should be checked at least annually by connecting a calibrated pressure gauge (available from ACI) to any one of the controller's pneumatic outlet connectors. Pressure accuracy of ± 10mmHg is adequate according to the most recent clinical studies, which are available from ACI upon request at no charge.

Check for overpressure alarm operation by increasing the regulator's output to 170mmHg ± 10mmHg with the pressure gauge attached. Alarm should activate after one second. Check for improper deflation alarm operation by temporarily plugging the outlets of the 6mmHg relief valves. Alarm should activate after 10 seconds.

Check the connectors and tubing sets at least annually for integrity and proper sealing and for possible kinking of the hoses. Also, inspect the power cord for damage and replace as necessary.

Clean the fan filter annually or every 8000 hours, whichever is sooner.

PATIENT'S INSTRUCTIONS FOR USE

Review the VHS/DVD and pictorial instructions that came with the device. If unavailable, follow the steps below.

STEP 1

- Set the controller by a chair for use in therapy. Plug the electrical cord into the controller and the wall outlet, with power switch in the off position. Be careful not to obstruct the air inlet, which is located on the side of the controller near the power cord inlet. Plug the other end of the power cord into a properly grounded AC wall outlet. Do not use an extension cord or a "cheater" adapter that eliminates the effect of the ground pin on the outlet plug. In health care facilities, used only AC outlets labeled "Hospital Grade."
- Plug the tubing set's dual connector into the controller's pneumatic outlet. Attach the tubing's barb connectors to the two elbow fittings on the cuffs by observing the FOOT and CALF labels.

STEP 2

- Note how the cuff is assembled when it arrives. The foot area is folded to create a sandal. Apply the cuff over a clean white sock with bandages left in place as described and pictured below.

  FOOT: Place the cuff open on the floor with the Velcro®-like hook tape facing up and the hose fittings facing down (Figure 2). Center your foot over the cuff (Figure 3). Bring the side straps over the top of the foot and attach them snugly with the Velcro®-like hook tape (Figure 4). Bring the back heel strap around the ankle and attach it (Figure 5).

  CALF: Center the remaining cuff behind your calf. Attach the upper and lower straps snugly around the front of the leg with Velcro®-like hook tape (Figure 6). Plug the barbed hose connector labeled **"TO FOOT"** into the lower cuff's hose fitting on the side of the ankle (Figure 7). Plug the barbed hose connector labeled **"TO CALF"** into the upper cuff's hose fitting behind the calf or use integral dual connectors. (Figure 8).

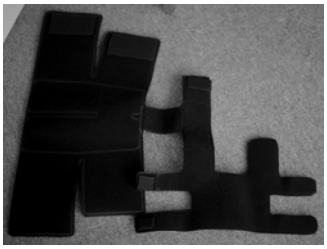

Figure 2

Figure 3

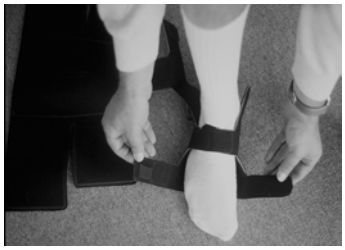

Figure 4

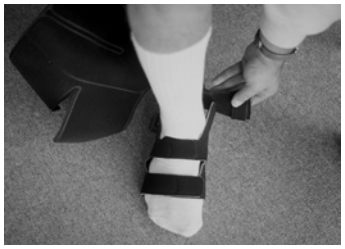

Figure 5

Figure 6

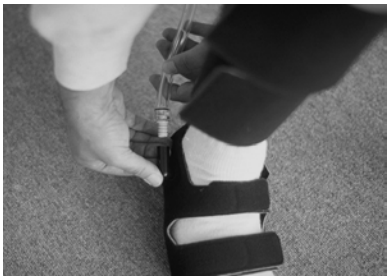

Figure 7

Figure 8

STEP 3

- Sit with feet on the floor and then turn on the power switch on the controller to begin therapy. Turn off the switch to end therapy or wait for the 1-hour "timed out" indicator depending on your prescription. Turn off power to stop the audible and visual indicators.
- It is recommended to use this device at least 3-4 hours a day, for 1 hour intervals or as instructed by your doctor. (Ideally: 60 minutes in the morning, 60 minutes in the afternoon, 60 minutes in the evening and 60 minutes before bedtime. For those who work or unable to work around the ideal schedule: 1-2 hours in the morning and 1-2 hours at night may be adequate). Consult your doctor and follow the prescribed schedule.

IMPORTANT:

- ❖ Call ACI with any questions before use at (888) 4 LEG FLO.
- ❖ Remove cuffs before walking or YOU MAY SLIP AND FALL.
- ❖ Report any adverse skin changes, pain, infection, or other medical issues to your doctor.
- ❖ This device is for use only on the prescribed patient. It is not to be used on others.
- ❖ ELECTRICAL HAZARD: Do not operate in wet areas or with wet hands, feet, etc.
- ❖ If you experience any problems with ArtAssist® controller, tubing, cuffs, or the electrical cord, please contact your local representative or ACI at (888) 4 LEG FLO.
- ❖ Please refer to the "Rental Agreement And Doctor's Prescription" that you and your physician signed for additional information.
- ❖ DO NOT MACHINE WASH THE CUFFS. WIPE WITH A MOIST CLOTH ONLY.

PACKING INSTRUCTIONS

Upon termination of your prescription by your doctor, return the device, the power cord, tubing, and the instructional videotape to ACI by using the Federal Express Airbill that was sent with the device. **Do not** send back the cuffs; they are yours to keep.

1. Carefully pack the controller with its top handle facing up and curved front panel matching the curved part of the front panel to the bottom packing foam. Put the top packaging foam over the top of the controller again, matching the curved part of the front panel to the packing foam.
2. Put the tubing, power cord and videotape into the white accessory box and slide it down into the slots in front of the controller's front panel (Figure 9).
3. Use the tape enclosed to seal the box, as shown in Figure 10.
4. Place the Federal Express Airbill that was sent with the ArtAssist® device on the top of the box, as shown below.
5. Telephone Federal Express at 1-800-GO-FEDEX (1-800-463-3339), then press the * key when connected.

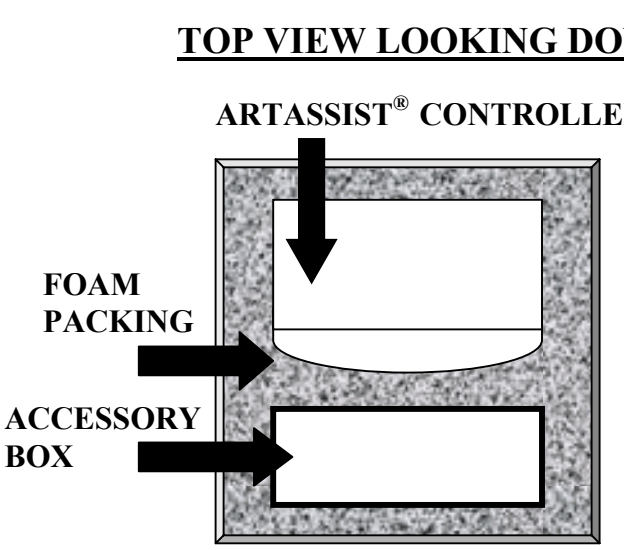

Figure 9

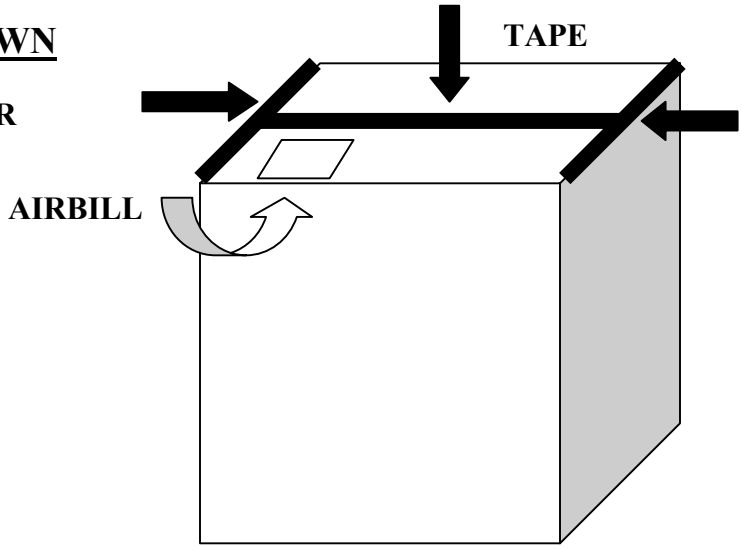

Figure 10

IMPORTANT: Keep all packing materials and use it to the device, power cord, VHS/DVD, and tubing to ACI.

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TROUBLESHOOTING

PATIENT

If the device is not operating:

1. Check if the power cord is plugged into both controller and wall outlet.
2. Is the power switch turned on and is the power switch illuminated?

If alarm indicators appear (to the right of the power switch):

1. Immediately stop use.
2. The audio alarm will sound with any visual indicator appearing.
   - **TIMED OUT** indicates the device has been continuously in use for about one hour. Cycle controller power to reset the one-hour timer and to continue use of the device, as prescribed.
   - **REPAIR LEAK** indicates an under pressure condition, most likely due to an air leak somewhere in the system. Check for leaks in the cuffs, tubing, and connectors. The pump may be malfunctioning or there may be a leak elsewhere in the system. It takes between 170 and 290 seconds of a leak condition to activate the alarm. A leak is considered significant if pressure is not able to exceed 60 mmHg.
   - **REPAIR** indicates that there is a problem in the system that is not leak related.
3. Next call ACI at 888 4 LEG FLO (888.453.4356).

If the cuff pressure feels weak:

1. Listen for air leaks in the cuffs.
2. Listen for air leaks in the tubes.
3. For rental customers, if there is a leak in the cuffs or the tubes, notify ACI Medical immediately. Cuffs and tubes will be replaced for normal wear and tear damage at no extra charge for customers renting the ArtAssist® device.
4. Check for kinked hose that prevents airflow to the cuff(s).

TRAINED SERVICE PERSONEL USE ONLY

If the device is not operating:

1. Check if the power cord is plugged into both controller and wall outlet.
2. Is the power switch turned on and is the power switch illuminated?
3. Disconnect power cord from controller and wall outlet. Open the front panel by removing the two screws on the bottom of the controller and lift up. First check if both 1A fuses (F1, F2) are intact and then check if the 5 Amp pump fuse (F3) is intact. If both are intact, then the next step is to call our service department at 888 4 LEG FLO.

If alarm indicators appear (to the right of the power switch):

1. Immediately stop use.
2. The audio alarm will sound with any visual indicator appearing.
   - **TIMED OUT** indicates the device has been continuously in use for about one hour. Cycle controller power to reset the one-hour timer and to continue use of the device, as prescribed.
   - **REPAIR LEAK** indicates an under pressure condition, most likely due to an air leak somewhere in the system. Check for leaks in the cuffs, tubing, and connectors. The pump may be malfunctioning or there may be a leak elsewhere in the system. It takes between 170 and 290 seconds of a leak condition to activate the alarm. A leak is considered significant if pressure is not able to exceed 60 mmHg.
   - **REPAIR** indicates that there is a problem in the system that is not leak related.
3. The REPAIR alarm indicates one of the following possible problems:
   1. Overpressure:
      - When pressure applied to the cuff is greater than 170mmHg for more than 1 second. Check the regulator setting using a calibrated pressure gauge, provided by ACI.
      - When compression cuffs do not deflate and remain at **≥ 30 mmHg** ± 10mmHg for **10 seconds**. Check for proper operation of solenoid valves and 6mmHg pressure relief valves.
   2. Pump temperature. If the pump motor temperature exceeds 58°C ± 2°C which may be caused by a pump failure or cooling fan failure.
   3. The 12-volt solenoid value supply. If it fails completely, it is unable to power the solenoid valves properly. Check power supply components (transformer, bridge rectifier, BR2 or filter capacitor C23).